The Economy of Tourniquets in the Operating Room

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Disclosures:

All authors are officers and stakeholders at Oneg HaKarmel Ltd., the manufacturer of HemaClear®.

Abstract

Introduction

Bloodless surgical field is used in the majority of limb operations in orthopedics, hand, plastics and in some vascular cases. This practice was started in 1873 by Dr. Friedrich von Esmarch with the elastic Esmarch Bandage and was improved in 1908 by Dr. Cushing who introduced inflatable cuffs as means to stop blood loss by a tourniquet. In the last 50 years or so the standard of care was to wrap the Esmarch Bandage from the distal to the proximal ends of the limb, followed by inflation of the cuff to a supra-systolic pressure.

In the last 12-15 years three major transitions have been noted:

1. Following the breakthrough 2006 paper by _____ et al who cultured reusable tourniquets and found 100% contamination, a trend started to use switch to using sterile tourniquets. This practice is now prevalent in at least a third of all Operating Rooms in the US with sterile disposable or sterile re-processed pneumatic cuffs.
2. The introduction of the Sterile Exsanguination Tourniquet (HemaClear®) which is an elastic device that combines near-perfect displacement of the blood from the limb (exsanguination), a silicone ring that blocks the return of blood into the limb and a sterile stockinet. This device can replace the pneumatic/Esmarch system with a single device that does not need any capital equipment (pump).
3. The economic climate in US healthcare with increased pressures to reduce overall costs by cutting down on hospital stay, reducing rate of surgical complications and the need to reduce cost of products used in surgery.

This paper compares the economics of #1 (pneumatic system) and #2 (HemaClear) within the constrains of #3 (need to reduce overall cost of healthcare. To do so, we shall first compare the direct costs of #1 and #2 followed by comparison of indirect costs and finally we shall carry out an economic review of the value of changes in hospital stay and complications when #1 and #2 are used.

Methods

The data presented in this paper are primarily extracted from websites of manufacturers and distributors. When relevant, we also used data from commercial sites of distribution organizations such as Medline and Henry Schein as well as from e-bay. Readers of this paper are encouraged to insert there own data in the template attached to the manuscript numbers negotiated by certain hospitals may differ from the prices disclosed on the Internet.

In order to calculate the economic impact of events that happen only in some of the patients (e.g. tourniquet pain), we first determined the cost of a single event “X” US$ and then multiplied by the prevalence or rate of occurrence of this event “f”. where f is a fraction (e.g. 0.4 for post op tourniquet pain after TKA). The cost calculation “C” was then determined as

C = f X.

The value of OR time was obtained from published data at USD/mi of OR time. The value of post op hospitalization day was also determined based on published data ( ) at USD per hospital day.

Results

Direct costs comparison: Table 1 shows the direct cost comparison between HemaClear and the two leading manufacturers of pneumatic tourniquets. Since this comparison is focused

on direct costs, it only includes the cost of cuff, Esmarch, stockinet and padding for the pneumatic tourniquet system.

Size\Product	HemaClear	Pneumatic cuff	Esmarch 4” or 6”	Stockinet	Webrol	Total
Small 14-28 cm	$35					
Medium 24-40 cm	$38					
Large 30-55 cm	$49					
XL 50-85 cm	$49					
Ankle	$27					
Forearm	$18.50					

Notes:

1. Non-sterile reusable tourniquet cuffs are not considered in this review as it is now known that all are contaminated ( ) and act as vectors for surgical site infection (SSI).
2. Re-processed tourniquet cuffs can be re-processed and re-used 4 times. Their cost is approximately 40-50% less than that of the single-use pneumatic cuffs shown in Table 1. Nearly 1.6 million Re-processed pneumatic cuffs were subject to a major recall by the FDA in 2016 (____) due to failed connectors leading to pressure loss and excessive bleeding by patients.
3. The linear size of the pneumatic cuffs does not correspond to the limb circumference since 4-6” of the length of the cuff must overlap to secure the Velcro®.
4. When Esmarch bandage is used on a large leg, it is often required to use 2 rolls for the case.

Additional direct costs

Additional direct costs are calculated by dividing costs occurring once or periodically in the lifetime of the pneumatic pump (not including interest on capital investment) and divided by the estimated number of uses during the period. Time saving is determined from published studies.

Size\ Product	Hema-Clear	Pneumatic pump	Tubes	Pump calibration	Preparation OR time	Application OR time	Total PT
Small 14-28 cm	None	$3[1]	$1.2[2]	$0.4[3]	5 min = $15	4 min = $12 min	$31.6
Medium 24-40 cm	None	$3[1]	$1.2[2]	$0.4[3]	5 min = $15	5 min = $15	$34.6
Large 30-55 cm	None	$3[1]	$1.2[2]	$0.4[3]	5 min = $15	5 min = $15	$34.6

XL 50-85 cm	None	$3[1]	$1.2[2]	$0.4[3]	5 min = $15	7 min = $21	$40.6
Ankle	None	$3[1]	$1.2[2]	$0.4[3]	5 min = $15	5 min = $15	$34.6
Forearm	None	$3[1]	$1.2[2]	$0.4[3]	5 min = $15	4 min = $12	$31.6

Notes:

1. There are no additional accessories when HemaClear is used
2. The time it takes to apply a HemaClear is less than 30 seconds (<$1.5).
3. The cost of replacing a pneumatic pump is $12,000-$18,000 ( ). This sum is divided by 4,000 to 6,000 uses during the pump lifespan.
4. Tubes that connect from the pump to the cuff are replaced every 300 – 400 uses ??? per manufacturer instructions.
5. The pumps must undergo maintenance and calibration periodically by a biomedical engineer or a certified technician. This process typically costs (~$600) and requires a down-time of the machine.
6. This analysis does not include the cost of personnel required in order to man the pump (set and change the pressure) during surgery.

Indirect costs

Indirect costs consist of the financial burden of complications and adverse effects of using a tourniquet during surgery. These include the direct cost to the hospital/payer, but do not include, in this analysis the costs incurred by the patient and his/her family due to complications and adverse effects. The following table lists these complications, an explanation of there causes and data on the prevalence and an estimate of the cost per case and a cost analysis normalized by the rate of each adverse effect.

Adverse effect	Explanation	Rate	Cost per case	Normalize cost based on rate
Post Op pneumatic tourniquet pain	Tourniquet pain delays discharge from hospital, increase need for physical therapy and increase the use of analgesics	39.7% (Karolinska) 34% Brazil ___ Ankara	Estimated 1 extra day in hospital = $1000	$397 $340
Post Op HemaClear Tourniquet pain	Tourniquet pain delays discharge from hospital, increase need for physical therapy and increase the use of analgesics	12% Brazil ___ Ankara	Estimated 1 extra day in hospital = $1000	$120 ___
Post Op pneumatic “Tourniquet Burn”	Blisters on tourniquet site, requiring skilled nursing, additional	20.7% Karolinska 6-24% New Zealand	Estimated 1 doctor visit, 2 nurse treatments plus	$120

	visits to clinic and medications		medications = $600	
Post Op HemaClear skin injury	Skin injury at HemaClear site	None		$0
Surgical Site Infection after pneumatic tourniquet	Post op Infection of the surgical site requiring IV antibiotics, extended hospital stay, revision surgery	12% Brazil 3.75% Ankara ___Karolinska Average 5%	$12,000 - $70,000 (Average $25,000)	$1,250
Surgical Site Infection after HemaClear	Post op Infection of the surgical site requiring IV antibiotics, extended hospital stay, revision surgery	2% Brazil 1.3% Ankara Average 1.5%	$12,000 - $70,000 (Average $25,000)	$375
Blood loss with pneumatic tourniquet	Intra and post-operative blood loss above threshold that requires transfusion	3.26 units Ankara – bilateral TKA		$100
Blood loss with HC	Intra and post-operative blood loss above threshold that requires transfusion	1.09 units Ankara – bilateral TKA		$30
Pneumatic Tourniquet neuropraxia	Nerve damage caused by pneumatic tourniquet	1:4200 cases (Norway JBJS 2006); 1:177 Mayo; 1:164 Karolinska study	$500,000 settlement of mal-practice suit	Assume 1:2000 we get $250 as normalize case rate cost
HC neuropraxia	Nerve damage caused by HD	None	zero	$0
Total PT				
Total HC				

Summary and discussion

We evaluated the economic benefit of using the sterile elastic exsanguination tourniquet vs. the use of the century-old pneumatic tourniquet system. We stratified the costs into 3 categories: Direct, Additional Direct and value of prevention of adverse effects. The table below is a summary of the three categories for the pneumatic tourniquet (PT) and HemaClear (HC):

Size\ Product	Direct HC Table 1	Direct HC additional	Indirect HC Table 3	Total HC cost	Direct PT Total Table 1	Direct PT additional Table 2	Indirect PT Table 3	Total PT cost
Average all models	$42	$0	$525	$567	$42	$34	%1990	$2066

The review of this table brings up the following observations:

1. Average Direct costs of HC and PT are the same
2. When additional Direct Costs are taken into consideration the cost of PT is 40% higher ($76) than that of HC ($42).
3. Indirect cost, which are primarily due to adverse effects are much greater than the direct costs and 4 fold greater with the pneumatic tourniquet than with HemaClear®.

This analysis is instructive from the point of view of the primary payer, e.g. medical insurance companies, Medicare and Medicaid. These are the ones who carry the overall burden of both direct costs (as part of DRG usually) and the cost of adverse effects. These 3rd party payers are trying to minimize adverse effects and re-admission for treating them by using administrative methods. However, this analysis shows that using means to counteract and reduce them can translate into huge cost savings if implemented across the board.

References